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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 10/597,804 | 08/08/2006 | Patrick M. Hughes | 17627(AP) | 6541 |
| 51957 | 7590 | 04/02/2009 | EXAMINER | |
| ALLERGAN, INC. | | | POLANSKY, GREGG | |
| 2525 DUPONT DRIVE, T2-7H | | | ART UNIT | PAPER NUMBER |
| IRVINE, CA 92612-1599 | | | 1614 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/597,804 | HUGHES, PATRICK M. | |
| | Examiner | Art Unit | |
| | GREGG POLANSKY | 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 December 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4 and 6-37 is/are pending in the application.
 - 4a) Of the above claim(s) 15-37 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4 and 6-14 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/22/2008</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of Claims

1. Applicants' response, filed 12/22/2008, to the Office Action mailed 6/23/2008 is acknowledged. Applicants canceled Claim 5, amended Claims 1 and 14 and page 12 of the Specification, and presented arguments in response to the Office Action.
2. Applicant's Information Disclosure Statement (IDS), filed 12/22/2008, is acknowledged and has been reviewed. The AstraZeneca document provided by Applicant has been considered, however, the citation for the document on the IDS contains a URL address that is incomplete. The URL address "http:emc.medicines.org.uk/emc/assets" does not link to the submitted document. Correction is requested.
3. Claims 1-4 and 6-14 are presently under consideration.
4. Applicants' arguments have been fully considered and are deemed to be persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-4 and 6-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Garst et al. (WO 2004/009583).

Garst et al. teach the compositions of instant Claims 8 and 10-14 and that these compounds have improved aqueous solubility and bioavailability. See Abstract; pages 208-209, claim 1; pages 213-216, claim 21, pages 217-218, claims 28-33. The pH ranges recited by the instant claims are merely a characteristic of an aqueous solution of the disclosed compounds. Since the compositions taught by Garst et al. are the same as those instantly claimed, one would expect, absent evidence to the contrary, that aqueous solutions of the compositions of Garst et al. will have the same pH as the corresponding claimed aqueous compositions. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v.*

Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) (“[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention”). Also see *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound “inherently” anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound “inherently results in at least trace amounts of” the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate).

Response to Arguments

7. Applicant argues the reference to Garst et al. does not teach an aqueous composition of the instantly claimed compounds, having a pH of about 5 to 7. Garst et al. teach intravenous administration of the compounds of their invention. The compounds were dissolved in phosphate buffered saline solution of pH 7.4. See page 43. Garst et al. teach an advantage of the disclosed prodrug proton pump inhibitors is that they may be “reconstituted to form an injectable liquid in a medium of approximately pH 7 to 8”. See page 33, last paragraph. The reference also teaches high aqueous solubility of the claimed compounds at pH 7.4. The compounds were less soluble at pH 3, but still more soluble than the prior art compounds (corresponding non-

prodrug proton pump inhibitor compounds). Garst et al. explains the higher solubility at pH 7.4 results from the formation of the sodium salt of the compounds at that pH. When the aqueous composition is pH 3, the compounds are less soluble because they are in the free carboxylic form. See pages 36-38. Further, the compounds taught by Garst et al. were tested for stability in buffered aqueous solutions of pH 3, pH 7, and pH 9. The highest stability was found at pH 7 (similar to the instantly claimed compounds).

Thus, Garst et al. teach aqueous compositions of the instant compounds. Garst et al., by testing at various pH values (i.e., 3, 7, and 9) determined optimal solubility and stability of the aqueous compositions to occur at about pH 7. Therefore, the reference teaches aqueous compositions of the instantly claimed compounds at pHs from 3-9 and determined the optimal pH of about 7 (i.e., optimal stability and solubility).

Conclusion

8. Claims 1-4 and 6-14 are rejected.
9. No claims are allowed.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614